UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,536	01/30/2004	Zaijie Wang	27611/38972A	8646

4743 7590 03/31/2006

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,536	WANG, ZAIJIE	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 are pending and subject to an Election/Restriction requirement.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a method of treating or preventing pain by administering an opiate analgesic and a calcium calmodulin dependent protein kinase (CaMKII) inhibitor, classified in various classes depending upon whether it is a protein 514, a nucleic acid 536, etc.

II. Claims 20-21, drawn to reducing, reversing or preventing tolerance to an opiate analgesic in an individual undergoing opiate analgesic therapy by administering CaMKII inhibitor, classified in various classes depending upon the inhibitor.

III. Claim 22, drawn to a method of reversing or preventing dependndence on an opiate analgesic by administering CaMKII inhibitor, classified in various classes depending upon the inhibitor.

IV. Claim 23, drawn to a method of treating opiate analgesic withdrawal by administering CaMKII inhibitor, classified in various classes depending upon the inhibitor.

V. Claims 24-26, drawn to a composition comprising CaMKII inhibitor and an opiate analgesic and an excipient, classified in various classes dependent upon the structure of the inhibitor.

VI. Claim27, drawn to a method of identifying an inhibitor of an inhibitor of CAMKII inhibitor by administering a candidate compound to a morphine tolerant mammal

and monitoring calcium calmodulin kinase expression in the mammal, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions V and I-IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the processes for using the products can be practiced with materially different products, i.e. the method of treating or prevent pain can be practiced with the materially different products aspirin or acetominophin; the of reducing, reversing or preventing tolerance to an opiate analgesic can be practiced with the materially different product by administering partial agonists of the NMDA receptor (See US Patent 5,523,323); the method of reversing or preventing dependence on an opiate analgesic can be practiced with the materially different product by administering partial agonist of the NMDA receptor (See US Patent 5, 523, 323); the method of treating opiate analgesic withdrawal can be practiced with the materially different product subutex or suboxone (See FDA Approves Two Drugs to Treat Opiate Dependence, Forbes, October 8, 2002, pg. 1, http://www.webprowire.com/summaries/266443.html, printed March 21, 2005); the method of identifying an inhibitor of CAMKII by administering a candidate compound to a morphine tolerant mammal can be practiced with a materially different product cell lines (See Specification pg. 11).

3. Searching the inventions of Groups I-IV together would impose serious search burden. The inventions of Groups I-V and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the composition and the various methods are not coextensive. Group V encompasses a vast plethora of molecules that range from chemicals to peptides to polypeptides to nucleotides to antisense for CaMKII inhibitors and then the plethora of opiate analgesics, the search for Groups I-IV and VI would require different text searching for the various methods of I) treating or preventing pain; II) reducing, reversing or preventing tolerance to an opiate analgesic in an individual undergoing opiate analgesic therapy; III) reversing or preventing dependence on an opiate analgesic in an individual undergoing opiate analgesic therapy; IV) treating opiate analgesic withdrawal and VI) identifying CaMKII inhibitors utilizing a mammal. Prior art which teaches the CaMKII inhibitor(s) and/or opiate analgesic(s) would not necessary be applicable to any of the methods. Moreover, even if the CaMKII inhibitor(s) and/or opiate analgesic(s) were known, the methods, which use the products may novel or unobvious in view of the preamble or active steps.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the are as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different method steps, restriction for examination purposes as indicated is proper.

4. Claims 1-26 are generic to the following disclosed patentably distinct species: 1) specific opiate analgesics and 2) specific calcium calmodulin dependent protein kinase inhibitors. The species are independent or distinct because 1) the specific opiate analgesics can be used for

different purposes, i.e. codeine can be used as a cough suppressant and hypnotic, dextromethorphan can be used as a cough suppressant, morphine hydrochloride can be use for the relief of coughing, diacetylmorphine (heroin) can be used as a hypnotic, meperidine can be used to treat drug induced rigors and post anaesthetic shivering, morphine can be used with congestive heart failure patients to decrease respiratory distress, opium is a hypnotic, methodone is used in drug rehabilitation,hydrocondone bitartatrate (vicodin) is also classified as a muscle relaxant (See Vicodin Addiction, 2004, pg. 1, http://www.vicodin-addiction.org/, printed March 29, 2006.), fentanyl can be used for anti-shiver and respiratory sedation (US 6,869,440), and the specific calcium calmodulin dependent protein kinase inhibitors have a variety of uses as set forth in the methods by Applicant. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for both the opiate analgesic and the CaMKII inhibitor for any elected Group, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, not that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

March 29, 2006